

Practitioner's Docket No. 01-2224

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK FFI E**

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

**OR**

In re application of: M. H. Dopson

Application No.: 0 9 /954,961

Group Art Unit: 1641

Filed: 09/18/2001

Examiner: Unknown

For: Transfer Factor Composition and Process for Producing Same

Assistant Commissioner for Patents  
Washington, D.C. 20231

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))**

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. § 1.97(b).

**CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. § 1.9(a))**

I hereby certify that this correspondence is, on the date shown below, being:

**MAILING**

☒ deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: 02/07/02

**FACSIMILE**

☐ transmitted by facsimile to the Patent and Trademark Office.

  
Signature

Maria Reichmanis

(type or print name of person certifying)

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NOTE: The "filing date of a national application" under 37 C.F.R. § 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 C.F.R. § 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. § 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. § 1.97(b)(2).

### IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

  
SIGNATURE OF PRACTITIONER

Maria Reichmanis

(type or print name of practitioner)

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Customer No.:



Practitioner's Docket No. 01-2224

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

the specification of which is being transmitted herewith

OR

In re application of: M. H. Dopson

Application No.: 09/954,961 Group No.: 1641

Filed: 09/18/2001

Examiner: Unknown

For: Transfer Factor Composition and Process for Producing Same

Assistant Commissioner for Patents  
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

**CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\***  
(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

37 C.F.R. § 1.8(a)

37 C.F.R. § 1.10\*

☒ with sufficient postage as first class mail.

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Mailing Label No. \_\_\_\_\_ (mandatory.)

**TRANSMISSION**

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Maria Reichmanis

(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by Express Mail **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Information Disclosure Statement [6-1]—page 1 of 11)

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NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last."

37 C.F.R. § 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.

**WARNING:** "No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(b).

### List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
  - 7A. ☐ EPO Search Report
  - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☒ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections , respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

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### **Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.



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## Section 2. Forms PT /SB/08A and 08B (formerly Form PTO-1449)

NOTE: With respect to the list required by paragraph (b) of 37 C.F.R. 1.98, the Notice of April 20, 1992 (1138 O.G. 37-41) points out that:

"The list may not be incorporated into the specification but must be submitted in a separate paper. A separate list is required so that it is easy to confirm that applicant intends to submit an information disclosure statement, and because it provides a readily available checklist for the examiner to indicate which identified documents have been considered. A copy of a separate list will also provide a simple means of communication to applicant to indicate the listed documents that have been considered and those listed documents that have not been considered. Use of form PTO-1449, "Information Disclosure Citation, is encouraged."

NOTE: "An information disclosure statement may include two list[s] (and two certifications[]). . . in situations where some of the information listed was cited in a communication from a foreign patent office not more than three months prior to filing the statement and some was not, but was not known more than three months prior to filing the statement." Notice of April 20, 1992 (1138 O.G. 37-41, 40).

NOTE: With respect to the examiner's consideration of the Information Disclosure Statement, the Notice of April 20, 1992 (1138 O.G. 37-41) states:

"If information is listed in the specification rather than in a separate paper, or if the other content requirements \*\*\* are not complied with, the examiner will notify applicant in the next Office action that the information has not been considered. It should be noted, however, that no copy of a U.S. patent application is required to be submitted. \*\*\* Where a U.S. patent application is properly cited, the examiner should obtain access to that file within the Office.

"Examiners must consider all citations submitted in conformance with the rules and this section and place their initials adjacent [sic] the citations on a list or in the boxes provided on a form PTO-1449. If the citations are submitted on a list other than a form PTO-1449, the examiner may write "all considered" and his or her initials to indicate that all citations have been considered. If any of the citations are considered, a copy of the submitted list or form, as reviewed by the examiner, will be returned to the applicant with the next communication. The original copy of the form will be entered into the application file. The copy returned to applicant will serve both as acknowledgement of receipt of the information disclosure statement and as an indication that the references were considered by the examiner. Forms PTO-326 and PTOL-37 include a box to indicate the attachment of form PTO-1449.

"Information which complies with requirements as discussed in this section but which is in a non-English language will be considered in view of the concise explanation submitted \*\*\* and insofar as it is understood on its face, e.g., drawings, chemical formulas, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches. The examiner need not have the information translated unless it appears to be necessary to do so. \*\*\* The examiner should not require that a translation be filed by applicant. The examiner should not make any comment such as that the non-English language information has only been considered to the extent understood, since this fact is inherent.

"Since information is required to be listed in a separate paper rather than in the specification, there is no need to mark "All checked" or "Checked" in the margin of a specification containing citations.

"If a statement fails to comply with the requirements as discussed in this section for an item of information, a line should be drawn through the citation to show that it has not been considered. The other items of information listed that do comply with the rules and this section will be considered by the examiner and will be appropriately initialed.

\* \* \* \* \*

"A citation listed on form PTO-1449 and considered by the examiner in accordance with this section will be printed on the patent. A citation listed in a separate paper, equivalent to but not on form PTO-1449, and considered by the examiner in accordance with this section will be printed on the patent if the list is on a separate sheet which is clearly identified as an information disclosure statement and the list lends itself to easy capture of the necessary information by the Office printing contractor, i.e., each item of information is listed on a single line, the lines are at least double-spaced from each other, the information is uniform in format for each listed item, the list includes a column for the examiner's initials to indicate that the information was considered. If a citation is not printed on the patent but has been considered by the examiner in accordance with this section, the patented file will reflect that fact . . . "



Approved for use through 9/30/98, OMB 0551-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

**Complete if Known**

*(use as many sheets as necessary)*

Sheet

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of

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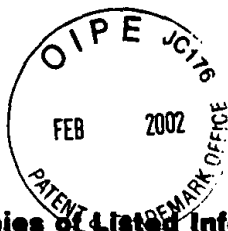
Attorney Docket Number

01-2224

[illegible][illegible]

**Date Considered**

**Burden Hour Statement:** This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**



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**Section 6. Copies of Listed Information Items Accompanying This Statement**

NOTE: 37 C.F.R. 1.98(a)(2) requires that any information disclosure statement filed under § 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . . "

NOTE: The wording in § 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

- ☐ Exception(s) to above:
  - ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
  - ☐ Cumulative patents or publications identified in Section 5.





**Section 9. Concise Explanation of English Language Listed Information Items (OPTIONAL)**

*NOTE: "Applicants may, if they wish, provide a concise explanation of why English-language information is being submitted and how it is understood to be relevant. Concise explanations are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more are highly relevant to patentability." Notice of April 20, 1992 (1138 O.G. 37-41, 38).*



The following patents are believed to be relevant to the subject application:

1. U.S. No. 5,883,224 issued March 16, 1989 to Kirkpatrick, et al. for Characterization of Transfer Factors and Methods of Use. Kirkpatrick, et al. disclose characterization of transfer factors in the form of amino acid and nucleic acid sequences corresponding to at least a portion of a conserved transfer factor region, and provide methods of use for diagnostic, therapeutic and other purposes.
2. U.S. No. 5,840,700 issued November 24, 1998 to Kirkpatrick, et al. for Methods of Producing Transfer Factor. Kirkpatrick, et al. disclose a process for preparing transfer factor from cell lysates, and the use of the transfer factor to treat infectious diseases.
3. U.S. No. 5,470,835 issued November 28, 1995 to Kirkpatrick, et al. for Transfer Factor and Methods of Use. Kirkpatrick, et al. disclose a process for preparing transfer factor from cell lysates, and the use of the transfer factor to treat infectious diseases.
4. U.S. No. 4,816,563 issued March 28, 1989 to Wilson, et al. for a Process for Obtaining Transfer Factor From Colostrum, Transfer Factor so Obtained and Use Thereof. Wilson, et al. disclose a process for obtaining antigen specific excreted transfer factor from colostrum, milk, or mammary tissue, and uses of the transfer factor in edible compositions, pharmaceutical compositions, and veterinary compositions.
5. U.S. No. 4,594,245 issued June 10, 1986 to Yoshida, et al. for Augmenting Factors for Human Antibody Production and Process for Preparing the Same. Yoshida, et

al. disclose augmenting factors for human antibody production having a molecular weight of 2,000–4,000 prepared from the supernatant of cultured human lymphocytes.

6. U.S. No. 4,435,384 issued March 6, 1984 to Warren for Transfer Factor Composition and Skin Treatment. Warren discloses a topical composition including transfer factor for dermatological treatment.

7. U.S. No. 4,132,776 issued January 2, 1979 to Jeter for Delivery of Immunologically Active Components of Transfer Factor. Jeter discloses dialyzable nucleopeptide leucocytic extracts (transfer factors) isolated from animals sensitized to selected antigenic substances, and administration of such extracts to the circulatory system of a recipient animal preferably through digestive tract tissue to enhance immunological competence.

8. U.S. No. 4,001,080 issued January 4, 1977 to Goust, et al. for Production of Immunological Materials. Goust, et al. product transfer factor by in vitro culture of lymphoblastoid cell lines after induction with transfer factor. The produced transfer factor is extracted from the cell lines.

9. U.S. No. 3,991,182 issued November 9, 1976 to Spitler, et al. for Transfer factor. Spitler, et al. disclose a method for treating human patients suffering from immune deficiency diseases by injecting transfer factor from leucocytes obtained from healthy donors who exhibit immune response to said diseases.

No attempt has been made to identify every relevant feature in the documents listed. The attached documents may contain relevant information other than that which

caused them to be selected and may be of interest with respect to one or more features of the applicant's invention(s). Accordingly, the Examiner is urged to review the documents identified and to form his or her own conclusions regarding the relevance thereof.

It is believed that the attached documents do not disclose or make obvious applicant's invention(s). Accordingly, examination of the claims on the merits and allowance of the application are earnestly requested.

Respectfully submitted,

DATE:

02/04/02



Maria Reichmanis  
Attorney for Applicant  
Reg. No. 37,220  
P.O. Box 3306  
Aiken, SC 29802  
Tel. (803) 641-1900



**Section 1 . Identification of Person(s) Making This Information Disclosure Statement**

The person making this statement is

*(check each applicable item)*

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

- ☐ supplied by the inventor(s).  
☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))  
☒ in the practitioner's file.

\_\_\_\_\_  
**SIGNATURE OF PRACTITIONER**

\_\_\_\_\_  
Maria Reichmanis

\_\_\_\_\_  
*(type or print name of practitioner)*

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